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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,848	01/17/2002	William R. Dubrul	ARTM 1008-6	3338
34263	7590 10/23/2003		EXAMI	NER
O'MELVENY & MEYERS 114 PACIFICA, SUITE 100			SERKE, CATHERINE	
IRVINE, CA 92618			ART UNIT	PAPER NUMBER
,			3763	1.0
			DATE MAILED: 10/23/2003	$\mathcal{O}$

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
,	Application No.	Applicant(s)				
Office Action Summer	10/051,848	DUBRUL, WILLIAM R.				
Office Action Summary	Examiner	Art Unit				
THE STATE OF THE S	Catherine S. Williams	3763				
The MAILING DATE of this communication Period for Reply	on appears on the cover sheet wit	n the correspondence address				
A SHORTENED STATUTORY PERIOD FOR F THE MAILING DATE OF THIS COMMUNICAT  - Extensions of time may be available under the provisions of 37 of after SIX (6) MONTHS from the mailing date of this communicat  - If the period for reply specified above is less than thirty (30) days  - If NO period for reply is specified above, the maximum statutory  - Failure to reply within the set or extended period for reply will, by  - Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).  Status	ION.  CFR 1.136(a). In no event, however, may a re ion.  s, a reply within the statutory minimum of thirty period will apply and will expire SIX (6) MONT at statute. cause the application to become AB/	ply be timely filed  (30) days will be considered timely, ITHS from the mailing date of this communication, ANDONED (35 U.S.C. § 133).				
1) Responsive to communication(s) filed o	n					
2a) This action is FINAL. 2b)	This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-26 is/are pending in the appli	cation.					
4a) Of the above claim(s) <u>9-17 and 19-26</u>	is/are withdrawn from considera	ation.				
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-8 and 18</u> is/are rejected.	6)⊠ Claim(s) <u>1-8 and 18</u> is/are rejected.					
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction	and/or election requirement.					
Application Papers						
9) The specification is objected to by the Exa		on Evaminos				
10) The drawing(s) filed on is/are: a)						
Applicant may not request that any objection 11) The proposed drawing correction filed on						
		sapproved by the Examiner.				
If approved, corrected drawings are required in reply to this Office action.  12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120	no Examinor.					
	foreign priority under 35 H.S.C. 8	\$ 119(a)-(d) or (f)				
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
•	ments have been received					
<ul> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> </ul>						
3. Copies of the certified copies of th						
	nal Bureau (PCT Rule 17.2(a)).					
14) Acknowledgment is made of a claim for do	omestic priority under 35 U.S.C.	§ 119(e) (to a provisional application).				
<ul><li>a)  The translation of the foreign language</li><li>15) Acknowledgment is made of a claim for de</li></ul>						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-9 3) Information Disclosure Statement(s) (PTO-1449) Paper I	48) 5) Notice of I	Summary (PTO-413) Paper No(s)  nformal Patent Application (PTO-152)  .				

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### **DETAILED ACTION**

### Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10 and 18, drawn to a device and method, classified in class 604,
   subclass 500.
- II. Claims 11-17, drawn to a method for removing particles, classified in class 606, subclass 200.
- III. Claims 19-26, drawn to a vascular prosthesis, classified in class 623, subclass 1.1.

  The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be practiced with another materially different product such as a combination of multiple catheters.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a braid with variable porosity. The subcombination has separate utility such as a vascular prosthesis that is not integral to a catheter.

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Inventions III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be practiced with another product such as by a combination of multiple catheters.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- means for moving the braided structure to an expanded condition by moving at least one of the tube and moving means, or
- 2. the braided structure being temperature sensitive so the braided structure is moveable to an expanded condition by heating the braided material.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are considered generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with John Kappos on 10/07/03 a provisional election was made with traverse to prosecute the invention of Invention I, claims 1-10 and 8. Further an election of species was also made with traverse to prosecute the species having means for moving the braided structure to an expanded condition by moving at least one of the tube and moving means (claims 1-8 and 18). Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-17 and 19-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The "alternating first and second braided section" have not been described in the specification or depicted in the drawings.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 7-8 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Daniel et al (US pat# 5,814,064). Daniel discloses a distal protection device. See figure 13A. The device includes an outer, hollow tube (124), a porous braided structure (130), and means for moving (132). The braided structure has a porous proximal side and a porous distal side with smaller pores. See figure 14A and 8:27-51. The distal side may also have a microporous membrane bonded or cast thereon. See 8:31-37.

Claims 1-3, 5, 7-8 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Hart et al (US Pat# 5,868,708). Hart discloses a distal protection device. See figure 10. The

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device includes an outer, hollow tube (12), a porous braided structure (36), and means for moving (18). The braided structure has a porous proximal side (64) and a porous distal side (72) with smaller pores. See figure 10. Figure 10 shows the alternating porous sections.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al.

Daniel meets the claim limitations as described above but fails to include the porous membrane being an elastic porous membrane. At the time of the invention, it would have been obvious to incorporate an elastic membrane into the invention of Daniel. Applicant has not disclosed that the elasticity of the membrane provides an advantage, is used from a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a non-elastic membrane or any porous membrane since the critical function of the membrane is for containing emboli.

## Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,258,115. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the invention is the same.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846.

The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke Williams October 7, 2003

BRIAN L. CASLER SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700